FEB 2 2 2001

K003268

510 (k) Summary of Safety and Effectiveness for z-touch

Manufacturer:

Adress: BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany
Phone: +49 89 99 15 68 0
Fax: +49 89 99 15 68 33

Contact Person: Mr. Rainer Birkenbach

Summary Date: December 18, 2000

Device Name:

Trade name: **z-touch**

Common/Classification Name: Instrument, Stereotaxic

Predicate Device:
Vector Vision® 2 (K-983831)
Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II

Indented Use:
z-touch is an additional device that works in conjunction with VectorVision® Navigation system and provides an additional option for patient registration.

Device Description:
z-touch allows semi-automatic correlation of preoperative image data to the actual patient.
z-touch is a cordless laser device that sends two different laser beams. These laser beams communicate with Vector Vision's passive camera system when scanning the surface of a patient. Surface points are being acquired and an algorithm matches the position of the acquired laser points to the pre-operatively scanned medical data sets, such as CT and MRI.

z-touch as feature of BrainLAB's image guided surgery system VectorVision® has been verified and validated according to BrainLAB's procedures for product design and development. The validation proves the safety and effectiveness of the system.

1 General Information

This is to notify you of the intention by BrainLAB AG to manufacture and market the following device:

	Date:	December 18, 2000
	Applicant:	Mr. Rainer Birkenbach BrainLAB AG Ammerthalstrasse 8 85551 Heimstetten GERMANY
	Tel.: Fax.:	+49 89 991568 0 +49 89 991568 33
a.	Trade Name:	Z-touch
b.	Common/Classification Name:	Instrument, Stereotaxic
c.	Establishment Registration Number:	804 39 33
d.	Manufacturing facility	See enclosed Table of Contents
e.	Classification:	Class II
	Performance Standards:	None established under Section 514
f.	Reason for Notification:	Marketing of a new device
g.	Substantial Equivalence:	This product is an additional part to the VectorVision² (BrainLAB Navigation System, K983831) developed and manufactured by BrainLAB. See enclosed table of contents for copies of the specification and labeling of this product.
h.	Compliance 513/514:	Not applicable
	Further information	Please do not hesitate to contact us if you have any more questions regarding this submission. Please contact with questions or requests for additional information our US office, ***BrainLAB USA, Inc.*** ***100 Marine Parkway*** ***Suite 305*** ***Redwood City, CA 94065*** ***USA***

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2001

Mr. Rainer Birkenbach
Executive Vice President
BrainLAB, AG
Ammerthalstrasse 8
85551 Heimstetten
Germany

Re: K003268
Trade Name: Z-Touch
Regulatory Class: II
Product Code: HAW
Dated: December 19, 2000
Received: December 21, 2000

Dear Mr. Birkenbach:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003268

Device Name: z-touch

Indications For Use:

z-touch works in conjunction with the VectorVision Navigation System. z-touch allows semi-automatic correlation of preoperative image data to the actual patient. The z-touch beam is being tracked by a camera system and the detected points matched to preoperative medical data such as CT and MRI.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format I-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003268